MAY - 6 2008

510 (K) SUMMARY

Prepared:	March 11, 2008
Submitter:	Serim Research Corporation
Address	P.O. Box 4002 Elkhart IN 46514
Phone: **Fax:**	574-264-3440 574-266-6222
Contact:	Patricia A. Rupchock Director of Regulatory Affairs
Device Trade Name:	SERIM® HiSENSE ULTRA 0.1™
Common or Usual Name:	Total Chlorine Reagent Strips
Device Classification Name:	Strip, Test, Reagent, Residuals for Dialysate, Disinfectant
Product Code:	MSY
Class:	II
Regulation Number:	876.5665
Substantial Equivalence:	The SERIM® HiSENSE ULTRA 0.1™ is substantially equivalent to Sterichek Sensitive Total Chlorine Reagent Strips; K001194
Device Description:	The device is a semi-quantitative or qualitative, single use, reagent test strip made up of a 0.20 inch square reagent pad that has been chemically treated to detect total chlorine (free chlorine/chloramines) in water. The pad is affixed to one end of a 3.25 inch by 0.20 inch white opaque polystyrene strip.
Intended Use:	SERIM® HiSENSE ULTRA 0.1™ Test Strips provide a convenient means for indicating the concentration of residual chlorine (chlorine bleach) detected in the solution used to rinse dialysate lines following disinfection of hemodialysis equipment. HiSENSE ULTRA 0.1 also provides a quick and convenient means for indicating low levels of total chlorine (chloramines/free chlorine) in water used to prepare dialysate.

Technological Characteristics: The SERIM® HiSENSE ULTRA 0.1™ Test Strips contain two indicators, a non-ionic surfactant, potassium iodide, and other inactive ingredients. Total chlorine (free chlorine/chloramines) reacts with the indicators to form a blue-purple complex. The amount of blue-purple color formed is dependent on the concentration of total chlorine in the sample. The color blocks on the label are related to chlorine concentration in terms of parts per million (ppm). The device is used to detect total chlorine concentrations between 0 and 3 ppm. The device will reliably detect concentrations of 0.1 ppm total chlorine.

Performance: The performance of the Serim HiSENSE ULTRA 0.1 Test Strips were evaluated using water samples in which either sodium hypochlorite or chloramines were added to give a range of total chlorine (free chlorine/chloramines) levels. The performance of the Serim HiSENSE ULTRA 0.1 Test Strips is substantially equivalent to the predicate device, SteriChek Total Chlorine Reagent Strips.

Conclusion: The Serim HiSENSE ULTRA 0.1 Test Strips have the same intended use as the predicate device. Both test strips measure the total chlorine (free chlorine/chloramines) levels in water. The Serim HiSENSE ULTRA 0.1 Test Strips have no characteristics that raise new types of safety or effectiveness questions. The Serim HiSENSE ULTRA 0.1 Test Strips can be used to monitor the level of total chlorine (free chlorine/chloramines) that may be present in water used to prepare dialysate. The test strips can also be used to detect residual chlorine levels in rinse water from dialysis equipment which had been disinfected with chlorine bleach.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY - 6 2008

Ms. Patricia Rupchock
Director of Regulatory Affairs
Serim Research Corporation
3506 Reedy Drive
ELKHART IN 46561

Re: K080712
Trade/Device Name: Serim® HiSENSE ULTRA 0.1™
Regulation Number: 21 CFR §876.5665
Regulation Name: Water purification system for hemodialysis
Regulatory Class: II
Product Code: MSY
Dated: March 11, 2008
Received: March 13, 2008

Dear Ms. Rupchock:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter.

21 CFR 876.xxxx	(Gastroenterology/Renal/Urology)	240-276-0115
21 CFR 884.xxxx	(Obstetrics/Gynecology)	240-276-0115
21 CFR 892.xxxx	(Radiology)	240-276-0120
Other		240-276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Nancy C Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

K080712

CONFIDENTIAL

INDICATIONS FOR USE

510(k) Number (if known): K080712

Device Name: Serim® HiSENSE ULTRA 0.1™

Indications For Use: SERIM® HiSENSE ULTRA 0.1™ Test Strips provide a convenient means for indicating the concentration of residual chlorine (chlorine bleach) detected in the solution used to rinse dialysate lines following disinfection of hemodialysis equipment. HiSENSE ULTRA 0.1 also provides a quick and convenient means for indicating low levels of total chlorine (chloramines/free chlorine) in water used to prepare dialysate.

Prescription Use √ AND / OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Nancy C Brogdon
(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K080712